K130287

MAY 30 2013

5. Traditional 510(k) Summary

The following 510(k) summary has been prepared pursuant to requirements specified in 21CFR§807.92(a).

807.92(a)(1) **Submitter Information:**	Rhythmlink International, LLC 1140 First Street South Columbia, SC 29209 Phone: 803-252-1222 FDA Registration #: 1067162 Owner Operator #: 9052354
Official Correspondent:	James M. Mewborne Manager of Regulatory Affairs Rhythmlink International, LLC 1140 First Street South Columbia, SC 29209 Phone: 803-252-1222 ext. 101 Email: jmewborne@rhythmlink.com
Summary Date:	January 22, 2013
807.92(a)(2) **Device Identification:**	**Proprietary Device Name:** MR Conditional Cup Electrode MR Conditional Webb Electrode (Trade name has not been finalized at this time) **Regulation Description:** Cutaneous Electrode **Review Panel:** Neurology **Product Code:** GXY **Regulation Number:** 21 CFR §882.1320, Cutaneous Electrode **Regulatory Class:** Class 2
807.92(a)(3) **Predicate Device(s):**	**K061148** Rhythmlink Cup Electrode

807.92 (a)(4) **Device Description:**	The design of the Rhythmlink Disposable MR Conditional Cup and Webb electrodes are identical to the existing Cup and Webb electrodes used to record neurological activity during electroencephalograph (EEG) and evoked potential (EP) procedures. The device consists of a disk shaped electrode with a Cup or Webb shape ABS molded plastic and coated with Ag/AgCl. The Electrode is permanently attached to a leadwire using a validated crimp process and is covered with a biocompatible heat shrink material. The Cup and Webb electrodes are connected to a10cm (100mm) long multi-strand copper cable with PVC insulation over the tinned copper conductors. An accessory cable is supplied to attach to the 10cm electrode leadwire to create 1.0 to 3.0 meter traditional lengths to attach to the monitoring equipment. This accessory cable is labeled "MR Unsafe" and is NOT intended to be in the MR environment. The significantly shorter 10cm lead wire is permanently attached to the electrode and reduces the effects of matching the electrode leadwire length to the wave length and reduces the likelihood of an increase in the heating effect. This will enable users to leave the electrodes in place during magnetic resonance imaging (MRI) procedures.
807.92(a)(5) **Intended Use / Indications for Use:**	The MR Conditional Cup and Webb Electrodes are intended for use in the recording of the Electroencephalogram (EEG), the evoked potential (EP), or as a ground and reference in an EEG or EP recording. This device is non-sterile for Single Patient Use Only and may remain on the patient in a MRI environment under specific conditions.
807.92(a)(6) **Technological Characteristics**	The main source of heating within the magnetic resonant imaging comes from the matching of the RF (radio frequency) wave lengths to the length of the electrode's leadwire. The reduction of the proposed device's leadwire length permanently attached to the electrode is the only physical change from the predicate device. This reduction in the cable length is to reduce the likelihood of heating effect from the RF component. The other issue is the torque produced by the magnetic field in the MR environment. The materials used in the MR Conditional Cup and Webb Electrodes are minimally affected by the magnetic field and the reduced leadwire length has shown a minimal heating effect from the radio frequency "E" field. The materials and manufacturing processes are identical to the predicate device **[K061148]** Rhythmlink Disc Electrodes.

807.92(b)(1) **Summary of Non-Clinical Tests**	In summary the MR Conditional Cup and Webb Electrodes are identical to the Predicate device Cup and Webb electrodes in materials, manufacturing processes and electrical performance. Bench tests where performed to determine if any changes had occurred in the manufacturing processes that would affect performance and they were found to predicate devices. There have been no design changes to the MR Conditional Cup and Webb Electrodes other than the length of the leadwire permanently connected to the electrode. These tests consisted of the following tests: ➢ Pull Tests of the leadwire to the electrodes' connection. ➢ Resistance testing of the completed assembly The mechanical and electrical bench testing confirmed the MR Conditional Cup and Web Electrode performs equal to the predicate devices and did not raise any additional questions of safety and efficacy. Additional testing was conducted by MR:comp Services on behalf of Rhythmlink International to determine the safety and efficacy of the proposed device within the magnetic resonance environment. In summary the numerical simulations were conducted in two phases. Phase one was to determine which of the three electrodes and modality would be the worst case configuration. The numerical simulations where completed using the SIMCAD X validated software with FDTD (Finite-Difference Time-Domain) modeling. The simulation plan consisted of three different electrode types: ➢ Cup Electrodes ➢ Webb Electrodes ➢ PressOn™ Electrode The numerical simulation tested all configurations of the three electrodes and found the PressOn™ electrode with two opposing leadwires to be the worst case configuration of the three types. All of the simulations used the same field strengths of 1.5T [68 MHZ] and 3.0T [128MHZ] for the final results. The second phase performed non-simulated physical testing within the MR equipment to replicate real world application as physically and economically feasible. The phantoms used for the physical testing where in accordance with appropriate ASTM Standards. The non-simulated physical testing also included Torque and Artifact testing and measuring. The simulation testing and the non-simulation MRI testing were shown to produce equivalent results. The temperatures in both the simulations and

	the real time tests only indicated a raise of 0.4C° at the area the electrodes are attached to the skin as measured directly under the electrode. The simulation indicated that the "Z" axis with two electrodes is the worst case in the "E" field which created the highest SAR and temperature change. Additional simulations and testing were completed to show the results of the complete leadwire (10cm) within the E field, different head sizes and populations. In summary all testing concluded that the proposed MR Conditional Cup and Webb Electrodes performed as expected and did not raise any new or additional questions of safety or efficacy.
807.92(b)(2) **Clinical Tests**	No Clinical Tests where conducted as referenced in 21 CFR 807.92(b)(2).
807.92(b)(3) **Clinical Summary**	No Clinical Tests where conducted as referenced in 21 CFR 807.92(b)(3).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

May 30, 2013

Rhythmlink International, LLC
Attn: James M. Mewborne
Manager of Regulatory Affairs
1140 First Street South
Columbia, SC 29209

Re: K130287
Trade Name: MR Conditional Cup Electrode, MR Conditional Web Electrode
Regulation Number: 21 CFR 882.1320
Regulation Name: Cutaneous Electrode
Regulatory Class: Class II
Product Code: GXY
Dated: February 2, 2013
Received: March 4, 2013

Dear Mr. Mewborne:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to: http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to: http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address: http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Joyce M. Whang -S

for Victor Krauthamer, Ph.D.
Acting Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K130287

Device Name: MR Conditional Cup Electrode, MR Conditional Webb Electrode

Indications For Use:

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Prescription Use __X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Joyce M. Whang -S

(Division Sign Off)
Division of Neurological and Physical Medicine Devices (DNPMD)

510(k) Number K130287